Kathy Krider Trier, Ph.D.

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Expertise

regulatory affairs & clinical research – pre and post market
biostatistics, database management
education and training, program design and evaluation
health care system

Summary

Successful professional with a proven track record in the medical device industry. Results oriented leader with organizational and interpersonal skills to develop industry leading work groups, both within the company and with outside professional organizations.

Professional Experience

3/2006 to date Corin USA Tampa, FL
(3/2008 to date) Vice President Clinical and Regulatory Affairs
(3/2006 to 3/2008) Director Clinical and Regulatory Affairs

- Manage the Regulatory, Clinical Research, Data Management Groups, Corin USA subsidiary
- PMA experience:
  - FDA approval PMA hip system: major amendment submissions, FDA Advisory Panel meeting
  - Post-PMA requirements: Post-PMA approval clinical studies, PMA Supplements & required reporting
  - FDA inspection & resolution of warning letters
- IDE experience:
  - Investigational Device Exemptions (IDEs): original IDE submissions and amendments, active IDE study management, study close out
  - Develop/implement FDA compliant database
- 510(k) submissions – hip & knee implants
- Health Canada license submissions
- Corporate:
  - Compliance and Ethics Committee
  - Clinical Research Review Committee
  - New product development
  - Product Complaints
  - ECRs, marketing literature review
  - SOPs, Work Instructions
- Industry:
  - Orthopedic Industry Representative on the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee of the FDA
  - Orthopedic Surgical Manufacturers Association (OSMA), Vice President
  - AAOS Orthopaedic Device Forum, member

1/2004 to 3/2006 DePuy Orthopaedics, Inc. Warsaw, IN
Manager, Clinical Research – Knee Group

- Knee group clinical studies including computer aided surgery, minimally invasive procedures: active post-market studies, Project Core Teams
- Clinical Research: protocol development, case report forms, investigator meetings, informed consent, IRB, site initiation, monitoring, data collection, adverse event reporting, study close, reports
- Electronic data capture: feasibility, implementation
- Reports, abstracts, white papers, manuscripts for publication
- Agreements, compliance, compensation
- SOPs, Work Instructions

7/2002 to 1/2004 DePuy Orthopaedics, Inc. Warsaw, IN
Senior Regulatory Affairs Associate

- Orthobiologics: Clinical research report CE Mark Class III Design Dossier, 510(k), feasibility IDE study, Project Core Team
- Regulatory submissions/filings hip & knee devices
- ECRs (engineering changes, label requests, process changes, supplier changes, nonconformities), marketing literature, abstracts, publications, surgical techniques

5/2001 to 7/2002 Biomet Orthopedics, Inc. Warsaw, IN
Regulatory Clinical Affairs Specialist

- PMA TMJ device: statistical analysis, Clinical Research Report
- IDE submissions: Class III & Non-Significant Risk IDE
- Clinical research studies

1984-2001 Indiana University - Purdue University Fort Wayne, IN
tenured faculty

- Statistics and research methods; medical sociology; nursing
- Director multidisciplinary research center
- Graduate program (program design, Indiana Commission on Higher Education approval)
- Consultant/Workshops/Trainer
- Teaching Awards
- Numerous articles, research reports, presentations, recognitions, awards

Other Relevant Experience

- AdvaMed Orthopedic Working Group

- ASTM: Mobile Bearing Knee Symposium, Guest editor STP Mobile Bearing Knee
- Editorial board for juried publication

Education

[redacted] Ph. D. Purdue University W. Lafayette, IN

- M.S. (Counseling); undergrad degrees (Sociology & Nursing) Licensed R.N.

References

- Upon request